

**To the ATTENTION of:
Hospital Personnel/ Distributor**

21 June 2016

URGENT FIELD SAFETY NOTICE– R419128
Prodisc-C Vivo Cervical Disc Prosthesis
Prodisc-C Vivo, uncemented convex, LD, 17x16mm, H5mm

Part Numbers	Part Description	Lot number
04.670.955S	Prodisc-C Vivo, uncemented convex, LD, 17x16mm, H5mm	9736836

Dear Sir/Madam,

Synthes GmbH is initiating a field safety notice of the above specified lot of Prodisc-C Vivo implants, which are a part of the Prodisc-C Vivo Cervical Disc Prosthesis System. Our records indicate that you may have devices in inventory that are in scope of this recall.

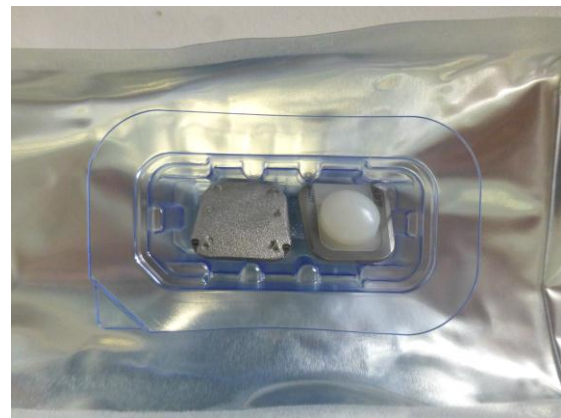
Reason for the Field Safety Notification

Synthes GmbH has recently discovered that Prodisc-C Vivo implants from the above mentioned lot may have been packaged incorrectly. The Tyvek lid that is affixed to the inner blister package may be missing for the above mentioned lot.

Prodisc-C Vivo implants are packaged sterile in a double barrier setup, with an outer foil package and an inner blister package. For the impacted lot, the Tyvek lid may be missing from the inner blister package. Due to the double barrier sterile packaging, the sterility of the implants will continue to be maintained when the Tyvek lid is missing.



Tyvek Lid of Prodisc-C Vivo Inner Blister Package



Prodisc-C Vivo Inner Blister Package with missing Tyvek Lid

Potential Patient Impact

The packaging nonconformance noted above has the potential to result in intraoperative surgical delay. When the outer foil pouch package is opened, the implant may dislodge from the uncovered blister package and has the potential to fall outside of the sterile field. Additional time may be required to obtain an alternative implant or device. There is no impact to the sterility of the implants within the impacted lot as sterility is maintained by the outer foil pouch. For patients with impacted Prodisc-C Vivo devices implanted, there is no recommendation for prophylactic removal. Patients should be monitored in accordance with standard practice for the Prodisc-C Vivo treatment process.

**To date there have been no reports of Patient Harm associated
with this packaging non-conformance.**

Customer immediate actions:

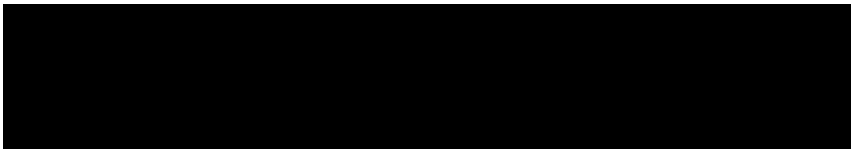
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Keep a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this Field Safety Notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes contact person.

Thank you for your attention and cooperation.

Synthes GmbH



Anne Brisson
Senior QA Manager, Product Safety and
Performance

Michael Jacene
Director, Quality Systems

Account Name: _____

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- We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.
- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

Returned devices (including lot number and quantity):

Name/Title (please print): _____

Address:

Phone Number: _____

Signature and Date: _____

Return Reference # (If applicable): _____

Please complete and return this page your local DePuy Synthes contact person

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.